IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: C. R. BARD, INC.,
PELVIC REPAIR SYSTEM
PRODUCTS LIABILITY LITIGATION MDL No. 2187

THIS DOCUMENT RELATES TO C. R. BARD WAVE 4 & WAVE 5 CASES BEFORE JUDGE GOODWIN:

MEMORANDUM OPINION AND ORDER
(*Daubert* Motion re: Brian Raybon, M.D.)

The defendant C.R. Bard, Inc. ("Bard") filed its Notice of Adoption of Motion to Exclude or Limit Certain Opinions and Testimony by Brian Raybon, M.D. in Wave 4 and 5 Cases ("Notice") [ECF No. 4574] in *In re C. R. Bard, Inc.*, *2:10-md-2187*, MDL 2187, on September 28, 2017. The defendant attached as exhibits to its Notice a motion and memorandum in support [ECF No. 4574-2] and reply brief [ECF No. 4692], which the defendant seeks to adopt and incorporate as its briefing for Waves 4 and 5. The paintiffs also adopted and incorporated by Notice of Adoption of Prior Daubert Response of Brian Raybon, M.D. for Waves 4 and 5 Cases, a brief in response to the defendant's Motion. [ECF No. 4597]. The court construes the defendant's Notice as a motion. As such, the Notice is now ripe for consideration because the briefing is complete. As set forth below, Bard's motion is **GRANTED in part** and **DENIED in part**.

I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 16,000 cases currently pending, approximately 1,500 of which are in the Bard MDL, 2187 MDL.

In this MDL, the court's tasks include "resolv[ing] pretrial issues in a timely and expeditious manner" and "resolv[ing] important evidentiary disputes." Barbara J. Rothstein & Catherine R. Borden, Fed. Judicial Ctr., *Managing Multidistrict Litigation in Products Liability Cases* 3 (2011). In an effort to manage the massive Bard MDL efficiently and effectively, the court decided to conduct pretrial discovery and motions practice on an individualized basis. To this end, I selected certain cases to become part of a "wave" of cases to be prepared for trial and, if necessary, remanded.

Upon the creation of a wave, a docket control order subjects each case in the wave to the same scheduling deadlines, rules regarding motion practice, and limitations on discovery. *See, e.g.*, Pretrial Order ("PTO") # 236 (establishing Wave 4); PTO # 244 (establishing Wave 5). To handle motions to exclude or to limit expert testimony pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the court developed a specific procedure for cases designated in Wave 4 and Wave 5. The court instructed the parties to file briefing on general causation issues in the main MDL, MDL 2187, while specific causation *Daubert* motions, responses,

and replies were to be filed in the individual member cases. To the extent that an expert is both a general and specific causation expert, the court advised the parties that they could file a general causation motion in the main MDL and a specific causation motion in an individual member case. *See* PTO # 236, at 4; PTO # 244, at 4.

Before plunging into the heart of the motion, and to clarify the record, I am compelled to comment on the manner in which the parties filed the instant *Daubert* motion and opposition. Similar to other *Dauberts* filed in the main MDL, Bard filed the instant motion as a "Notice" adopting and incorporating the entirety of a motion and its corresponding papers filed in a previous case before the court. The plaintiffs, likewise, filed their opposing briefs in conjunction with a "Notice." The parties then attached the substance of their briefs, i.e., the supporting or opposing memorandum of law, as an exhibit to the Notice. So, for example, Bard's *Daubert* motion and its memorandum in support are attached as Exhibit B to the Notice. Exhibit B also integrates other vital supporting papers into same exhibit, such as the expert report or deposition transcripts, demarcated rather confusingly within Exhibit B as "Exhibit A" and "Exhibit B" respectfully, forming one large document. With this in mind, the court turns its attention to the present dispute.

II. Legal Standard

Under Federal Rule of Evidence 702, expert testimony is admissible if it will "help the trier of fact to understand the evidence or to determine a fact in issue" and (1) is "based upon sufficient facts or data" and (2) is "the product of reliable principles

and methods," which (3) has been reliably applied "to the facts of the case." Fed. R. Evid. 702. A two-part test governs the admissibility of expert testimony. The evidence is admitted if it "rests on a reliable foundation and is relevant." *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579, 597 (1993). The proponent of expert testimony does not have the burden to "prove" anything. However, he or she must "come forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998).

The district court's role as gatekeeper is an important one. "[E]xpert witnesses have the potential to be both powerful and quite misleading"; the court must "ensure that any and all scientific testimony . . . is not only relevant, but reliable." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. at 588, 595; *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999)). I "need not determine that the proffered expert testimony is irrefutable or certainly correct. As with all other admissible evidence, expert testimony is subject to testing by '[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.'" *United States v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006) (alteration in original) (citation omitted) (quoting *Daubert*, 509 U.S. at 596); *see also Md. Cas. Co.*, 137 F.3d at 783 ("All *Daubert* demands is that the trial judge make a 'preliminary assessment' of whether the proffered testimony is both reliable . . . and helpful.").

Daubert mentions specific factors to guide the overall relevance and reliability determinations that apply to all expert evidence. They include (1) whether the

particular scientific theory "can be (and has been) tested"; (2) whether the theory "has been subjected to peer review and publication"; (3) the "known or potential rate of error"; (4) the "existence and maintenance of standards controlling the technique's operation"; and (5) whether the technique has achieved "general acceptance" in the relevant scientific or expert community. *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003) (quoting *Daubert*, 509 U.S. at 593-94).

Despite these factors, "[t]he inquiry to be undertaken by the district court is 'a flexible one' focusing on the 'principles and methodology' employed by the expert, not on the conclusions reached." *Westberry*, 178 F.3d at 261 (quoting *Daubert*, 509 U.S. at 594-95); *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999) ("We agree with the Solicitor General that '[t]he factors identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony.'" (alteration in original)); *see also Crisp*, 324 F.3d at 266 (noting "that testing of reliability should be flexible and that *Daubert*'s five factors neither necessarily nor exclusively apply to every expert").

With respect to relevancy, *Daubert* also explains:

> Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful. The consideration has been aptly described by Judge Becker as one of "fit." "Fit" is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes. . . . Rule 702's "helpfulness" standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.

Daubert, 509 U.S. at 591-92 (citations and internal quotation marks omitted).

III. Analysis

Dr. Raybon is a board-certified physician in obstetrics and gynecology, specializing in female pelvic and reconstructive surgery since 1998.

A. Bard's Knowledge or State of Mind

First, Bard argues that I should preclude Dr. Raybon from testifying as to Bard's knowledge or state of mind. I agree; experts may not testify about what other parties did or did not know. However, to the extent Bard seeks to exclude Dr. Raybon's testimony about factual issues or the knowledge of the medical community in general, I disagree. Expert witnesses may properly offer opinions on these topics. Therefore, Bard's motion is **GRANTED** to the extent that it seeks to exclude evidence regarding Bard's knowledge or intent.

B. Legal Conclusions

Second, Bard contends that Dr. Raybon seeks to offer testimony constituting various legal opinions. Throughout these MDLs, the court has prohibited the parties from using experts to usurp the jury's fact-finding function by allowing testimony of this type, and I do the same here. *See, e.g.*, *In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013); *see also, e.g.*, *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006) ("[O]pinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible."). Additionally, an expert may not offer expert testimony using "legal terms of art," such as "defective," "unreasonably dangerous," or "failure to warn." *See Perez v. Townsend Eng'g Co.*, 562 F. Supp. 2d 647, 652 (M.D. Pa. 2008). Thus, to the extent that Dr. Raybon's opinions

constitute legal conclusions, those opinions are **EXCLUDED**. Bard's motion is **GRANTED** on this point.

C. Physician Training

Third, Bard seeks to exclude Dr. Raybon's opinion that Bard's physician training program was inadequate. Bard argues that because Dr. Raybon's opinions on physician training depend on the competence of other physicians, it should be excluded under *Daubert* as irrelevant. Relevance under *Daubert* depends on whether "a valid scientific connection" exists between the expert's testimony and the facts or issues of the case. *Daubert*, 509 U.S. at 591-92. Here, I cannot detect such a connection. Whether Bard admitted into its training programs certain physicians whom Dr. Raybon considers as "undertrained" says little about the design of the Avaulta or the adequacy of its warnings. *See, e.g.*, *Sanchez v. Bos. Sci. Corp.*, No. 2:12-cv-05762, 2014 WL 4851989, at *32 (S.D. W. Va. Sept. 29, 2014) (excluding an expert's opinion on physician training because it "primarily focus[es] on the competence of other physicians, which is irrelevant and will not assist the jury in determining the issues in this case"). Therefore, Dr. Raybon's opinions on physician training are **EXCLUDED** as irrelevant. Bard's motion on this point is **GRANTED**.

D. Adequacy of Warnings

Fourth, Bard seeks to exclude Dr. Raybon's opinion that the Avaulta Instructions for Use ("IFU") failed to provide adequate warnings. Bard asserts that Dr. Raybon lacks the qualifications necessary to render this opinion, given that he is not an expert in product labeling. The plaintiffs respond that Dr. Raybon's experience

as Bard's Key Opinion Leader qualifies him "to render an opinion regarding the IFU's completeness, accuracy, and the extent to which any inaccuracies or omissions could either deprive a reader or mislead a reader of what the risks and benefits are or were at the time the labeling was published." Pls.' Resp. to Bard's Mot. to Exclude or Limit Certain Ops. & Test. of Brian Raybon, M.D. 15 [ECF No. 4597-1].

Dr. Raybon has not demonstrated experience in the requirements for product labeling, and as such, he may not testify as to what the Avaulta label should or should not have included under the law. However, as an experienced urogynecologist, he may testify about the risks he perceives that the Avaulta poses to patients and then opine that the Avaulta IFU did not convey those risks. *See In re Yasmin & Yaz (Drospirenone) Prods. Liab. Litig.*, 2011 WL 6301625, at *11 (S.D. Ill. Dec. 16, 2011) ("[D]octors are fully qualified to opine on the medical facts and science regarding the risks and benefits of drugs and to compare that knowledge with what was provided in the text of labeling and warnings . . . ." (brackets and internal quotation marks omitted)). To the extent that Dr. Raybon's opinions fit within this comparison, they are not excluded at this time. Bard's motion on this issue is **DENIED**.

E. Product Design

Fifth, Bard seeks to exclude Dr. Raybon's opinions about the design of the Avaulta, including the characteristics of polypropylene and the insertion method of the device, on the grounds that Dr. Raybon is unqualified to offer these opinions and that the opinions lack a reliable basis. With respect to Dr. Raybon's qualifications, I disagree with Bard. Dr. Raybon has extensive experience with POP and the use of

mesh as a form of treatment. Moreover, he has direct experience with the Avaulta products as a consultant for Bard. In this role, Dr. Raybon tested the Avaulta products on cadavers and taught training courses on the use and implantation of the Avaulta. This knowledge of and experience with POP devices and, more specifically, Avaulta products, qualifies him to opine on the design of the Avaulta and the polypropylene used to construct it. *See* Fed. R. Evid. 702 (stating that a witness may be "qualified as an expert by knowledge, skill, experience, training, or education"); *see also, e.g.*, *In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 612 (S.D. W. Va. 2013) (ruling that a urogynecologist was qualified to opine on product design and biomaterials because he had "extensive experience with pelvic floor disorders and the use of mesh to treat such disorders"). Therefore, I **FIND** that Dr. Raybon is qualified to opine on product design. Bard's motion on this point is **DENIED**.

With respect to the reliability prong of *Daubert*, Bard disputes the basis for eight of Dr. Raybon's opinions on the design of the Avaulta. In general, Bard criticizes Dr. Raybon's significant reliance on internal corporate documents in reaching his conclusions and his inability during deposition to cite peer-reviewed literature to support his opinions. First, though an expert may not simply narrate corporate documents in front of the jury, he may rely on such information in forming and supporting his opinions. *See, e.g.*, *Sanchez*, 2014 WL 4851989, at *4 (holding that an expert "may testify about his or her review of internal corporate documents solely for the purpose of explaining the basis for his or her opinions"); *In re Mentor Corp. ObTape Transobturator Sling Prods. Liab. Litig.*, 711 F. Supp. 2d 1348, 1368 (M.D.

Ga. 2010) ("[T]he experts' reliance on the journal articles and [the defendant's] internal documents does not diminish the weight that the Court gives to the experts' opinions, assuming that the opinions are otherwise sufficiently reliable."). For the most part, Dr. Raybon has properly used Bard's internal documents to develop and reinforce his opinions rather than to narrate Bard's corporate conduct. Furthermore, many of the internal documents relied upon by Dr. Raybon could stand alone as medical research and literature. For these reasons, I do not consider Dr. Raybon's reliance on corporate documents as problematic.

In addition, given that Dr. Raybon has demonstrated in his report that his opinions have literary support, I decline to exclude his opinions on the basis that he was unable to recall the literature during his deposition. At trial, Bard can certainly expound upon any errors or inconsistencies that it extracted during Dr. Raybon's deposition. *See Daubert*, 509 U.S. at 596 ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.") But because Dr. Raybon has undeniable experience on this subject matter and has substantiated his opinion with testable, peer-reviewed literature, I must open the gates to his testimony. Bard's motion on this point is **DENIED**.

F. Complications

Sixth, Bard argues that the court should exclude Dr. Raybon's opinions on the complications he has seen in patients implanted with the Avaulta because they rest on unverified and "anecdotal" estimates of a complication rate. *See* Bard's Mem. in

Supp. of Mot. to Exclude or Limit Certain Ops. & Test. of Brian Raybon, M.D. 17 [ECF No. 4574-2]. In response, the plaintiffs maintain that Bard has mischaracterized Dr. Raybon's testimony and that Dr. Raybon "does not purport to offer any opinion regarding any 'complication rate.'" Pls.' Resp. to Bard's Mot. to Exclude 18. Bard has subsequently accepted this clarification, agreeing that Dr. Raybon can "describe the types of complications he has seen with the Avaulta and how they are treated," so long as he does not rely on "self-described 'wild guesses' about his anecdotal Avaulta complication rates." Bard's Reply in Supp. of Mot. to Exclude or Limit Certain Ops. & Test. of Brian Raybon, M.D. 9 [ECF No. 4692-2].

I agree that if Dr. Raybon's opinion is limited in this way, it survives *Daubert*'s scrutiny. That is, Dr. Raybon may testify about the complications he has observed in patients implanted with the Avaulta (without referring to complication rates), but, as I explained in *Eghnayem, et al. v. Boston Scientific Corp.*, he lacks the qualifications to infer conclusions from these observations as to the etiology of complications associated with a pelvic mesh device:

> Federal Rule of Evidence 702 allows a witness to provide expert testimony only to the extent that the testimony draws from the expert's knowledge and expertise. Fed. R. Evid. 702 advisory committee notes. . . . Dr. Raybon's opinion testimony [] goes beyond his experience with pelvic mesh. He is not a specialist in the etiology of pelvic and vaginal pain, and his awareness of any relationship between nerve trauma and mesh products is limited to his experience in diagnosing fifteen to twenty post-implantation patients. Accordingly, Dr. Raybon's knowledge, though extensive with respect to the mechanics of pelvic surgery, does not qualify him to opine on the cause of nerve trauma in the pelvis. *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) ("A court may conclude that there

> is simply too great an analytical gap between the data and the opinion proffered.").

No. 2:13-cv-07965, 2014 WL 5320566, at *35 (S.D. W. Va. Oct. 27, 2014). This holding equally applies to this case. To the extent that Dr. Raybon's opinions go beyond his observations and into an assessment of the general causal relationship between pelvic pain (or other complications) and the Avaulta, they are **EXCLUDED**. Bard's motion on this point is **GRANTED in part** and **DENIED in part**.

G. Product Testing and Clinical Trials

Next, Bard seeks to exclude Dr. Raybon's opinions on Bard's pre- and post-market testing of the Avaulta and the potential results of clinical trials. Bard argues that Dr. Raybon is unqualified to opine on what Bard should have done in terms of product testing, and that his opinion on the potential results of clinical trials is purely speculative. I agree. There is no indication in Dr. Raybon's expert report or otherwise that he has any experience with or knowledge about the appropriate testing that a medical device manufacturer should undertake. His experience as a pelvic surgeon does not qualify him to speak on this matter, *see, e.g.*, *Edwards v. Ethicon, Inc.*, No. 2:12-cv-09972, 2014 WL 3361923, at *17 (S.D. W. Va. July 8, 2014) (excluding the opinions of Drs. Blaivas and Rosenzweig on the topic of medical device premarket testing because their work as urogynecologists and urologists does not give them knowledge on product testing), nor does his experience with training others on how to use the Avaulta, a role that did not require him to participate in clinical testing or clinical trials.

Because Dr. Raybon has no demonstrated training in, knowledge of, or experience with the design of clinical trials or the process of testing medical devices, his opinions fall short of Rule 702 and cannot be admitted. *See* Fed. R. Evid. 702 (stating that an expert must be "qualified . . . by knowledge, skill, experience, training, or education"). Bard's motion on this point is **GRANTED**.

H. Specific Causation Opinions

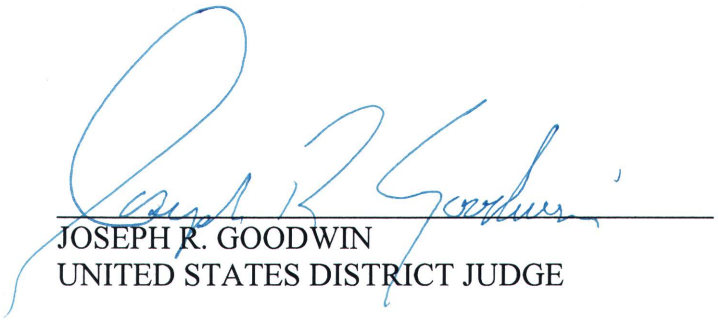
Finally, Bard argues that Dr. Raybon's specific causation opinions must be excluded because they derive from his unreliable general causation opinions. The admissibility of an expert's specific causation opinions must be assessed on a case-by-case basis. *See* PTO # 236, ¶ B.1 ("Specific causation *Daubert* motions, responses and replies must be filed in the individual member cases."). Therefore, the court will not address specific causation arguments filed in the main MDL. Bard's motion on this point is **DENIED**.

IV. Conclusion

To summarize, Bard's Notice of Adoption of Motion to Exclude or Limit Certain Opinions and Testimony by Brian Raybon, M.D. in Wave 4 and 5 Cases [ECF No. 4574], which the court has construed as a motion, is **GRANTED in part** and **DENIED in part** consistent with my reasoning above.

The court **DIRECTS** the Clerk to file a copy of this Memorandum Opinion and Order in 2:10-md-2187, and the Bard Wave 4 and Wave 5 cases identified in the Exhibit attached hereto. The court further **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: September 5, 2018



JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

Exhibit A

CIVIL ACTION NUMBER	Case Name
2:14-cv-03439	Kitchen v. C. R. Bard, Inc. et al.
2:14-cv-18890	McManus v. C. R. Bard, Inc. et al.
2:14-cv-21874	McCray v. C. R. Bard, Inc. et al.
2:14-cv-23401	Barber v. C. R. Bard, Inc. et al.
2:14-cv-28943	Smith et al. v. C. R. Bard, Inc. et al.
2:16-cv-01855	Eiffler v. Sofradim Production SAS et al.